**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**

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| MSP RECOVERY CLAIMS SERIES 44, LLC, and MSP RECOVERY CLAIMS, SERIES LLC,<br><br>Plaintiffs,<br><br>v.<br><br>PFIZER, INC.,<br><br>Defendant. | Case No. _____<br><br>**Class Action Complaint**<br><br>**Jury Trial Demand** |

## CLASS ACTION COMPLAINT

MSP Recovery Claims Series 44, LLC ("Series 44"), and MSP Recovery Claims, Series LLC ("MSPRC") (collectively, "Plaintiffs"), on behalf of a class of similarly situated third-party payers ("TPPs"), file this Class Action Complaint against Defendant, Pfizer, Inc., to seek economic damages for those TPPs that paid or made reimbursements for non-merchantable drugs that were unlawfully manufactured, distributed, or introduced into the market by Defendant Pfizer.

## INTRODUCTION

1. This case arises from adulterated, misbranded, or unapproved varenicline-containing drugs ("VCDs") that were designed, manufactured, marketed, distributed, packaged, or ultimately sold by Defendant Pfizer in the United States under the brand name Chantix®. These VCDs are non-merchantable and are not of the quality that the Defendant Pfizer represented.

2. The brand name drug Chantix is known generically as varenicline and is a partial

nicotine agonist. It is a first-line therapy in the treatment to help quit smoking. Unlike many other smoking-cessation aids, Chantix does not contain nicotine.

3. Pfizer obtained approval from the United States Food and Drug Administration ("FDA") to sell Chantix as a first of its kind treatment in May 2006.

4. Chantix quickly became one of Pfizer's fastest growing products. Major media spending on Chantix totaled approximately $55 million in 2007 (the year after its approval). In the year Chantix launched, Pfizer spent approximately $4.3 million in medical journal advertisements alone.

5. The market rapidly embraced Chantix and continues to do so to this day. For example, from its launch through 2015, the number of Chantix prescriptions for Medicaid beneficiaries increased 13,277%.[1]

6. The price for Chantix has also steadily climbed since its launch. Price estimates at launch were approximately $113.98 climbing to $254.50 in 2015. By 2018, the price had more than doubled to $485 for a 30-day supply, bringing in $997 million in sales that year.[2]

7. The market for smoking-cessation treatments remains strong with sales of Chantix at approximately $919 million for last year alone. Chantix remains one of the few, and most prevalent, smoking-cessation drug treatments, and one of Pfizer's top drug products. Pfizer's extended patent protection on Chantix ensures exclusivity through at least August 2022.

8. At all pertinent times for purposes of this action, Defendant Pfizer represented and warranted to consumers that its VCDs (that is, what it purports to be Chantix) were

[1] Xiaomeng Yue, et al., *Trends in Utilization, Spending, and Prices of Smoking-Cessation Medications in Medicaid Programs: 25 Years Empirical Data Analysis, 1991–2015*, AM. HEALTH DRUG BENEFITS, Sept. 2018, at 275-285, www.ncbi.nlm.nih.gov/pmc/articles/PMC6207314/.
[2] Arlene Weintraub, *Price of Pfizer's smoking-cessation drug Chantix doubles in just 5 years: report*, FIERCE PHARMA (June 26, 2018), https://www.fiercepharma.com/pfizer-hikes-price-smoking-cessation-drug-chantix-106-5-years-report.

therapeutically equivalent to, and otherwise the same as, the actual FDA-approved brand name drug Chantix. Specifically, Defendant Pfizer represented and warranted that the VCDs were fit for their ordinary uses, met the specifications of Defendant's FDA-approved labeling materials, and that it manufactured and distributed the VCDs in accordance with all applicable laws and regulations.

9. Defendant willfully disregarded these standards, and knowingly and fraudulently manufactured, sold, labeled, marketed, or distributed adulterated or misbranded VCDs for purchase in the United States by consumers.

10. Defendant's VCDs were adulterated, misbranded, or both (and thereby rendered worthless), through contamination with a probable human carcinogen known as N-nitroso-varenicline. Additionally, Defendant was on notice of other potential contamination from nitrosamines such as N-nitrosdimethylamine ("NDMA") and N-nitrosodiethlamine ("NDEA").

11. According to the FDA and other global health authorities, nitrosamines are dangerous probable human carcinogens.

12. According to FDA testing, Defendant's VCDs contained nitrosamine levels many times higher than the FDA's updated interim limits for nitrosamine impurities.

13. On July 2, 2021, and July 19, 2021, Pfizer began recalling its VCDs "because [the product] may contain levels of a nitrosamine impurity, called N-nitroso-varenicline, above FDA's acceptable intake limit."[3] The FDA has yet to release full testing results for other nitrosamine impurities. On September 16, 2021, Pfizer extended its recall to all Chantix.[4]

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[3] *FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)*, U.S. FOOD & DRUG ADMIN. (July 2, 2021 & July 19, 2021), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix.

[4] *Pfizer Expands Voluntary Nationwide Recall to include All Lots of CHANTIX® (Varenicline) Tablets Due to N-Nitroso Varenicline Content*, U.S. FOOD & DRUG ADMIN. (Sept. 16, 2021), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-

14. On information and belief, N-nitroso-varenicline contamination of Defendant's VCDs dates back many years, at which point Defendant had actual or, at a minimum, constructive notice of the contamination.

15. Ironically, the Defendant's wrongful acts caused those people trying to use smoking products *less* to take a pill containing carcinogens similar to those contained in cigarettes.

16. Plaintiffs' assignors paid for VCDs that were illegally and willfully introduced into the market by Defendant, which caused them and hundreds of other TPPs paying for or reimbursing prescriptions for these VCDs to sustain substantial economic damages. Defendant's VCDs were not fit for their ordinary use and Defendant has been unjustly enriched through the sale of these knowingly adulterated and misbranded drugs. Defendant's conduct, as detailed in this Complaint, also constitutes actionable common law fraud, consumer fraud, and violates state and federal law.

## PARTIES

17. Plaintiff Series 44 is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Series 44's Amended and Restated Limited Liability Company Operating Agreement dated October 23, 2020, permits Series 44 to establish one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Series 44 established various designated series to serve as units of the company to maintain various claims recovery assignments separate from other company assets, and to account for and associate certain assets with certain particular series.

nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n.

18. Series 44 has enumerated rights relating to its designated series under its Amended and Restated Limited Liability Company Operating Agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c).

19. Specifically, all rights and benefits arising from assignments to its series (including the assignments discussed below) belong to Series 44. Series 44 is authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series under its Amended and Restated Limited Liability Company Operating Agreement. Series 44 retained the legal right to sue on behalf of each designated series and pursue all rights, benefits, or causes of action arising from assignments to a series in its own name or in the name of the designated series. Certain Medicare Advantage plans and healthcare benefit providers have assigned their recovery rights to assert the claims alleged in this Complaint to series of Series 44. As such, Series 44 has the right and power to sue Defendant to recover the payments at issue in this action.

20. Plaintiff MSPRC is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. MSPRC's Amended and Restated Limited Liability Company Operating Agreement effective March 27, 2018, permits MSPRC to establish one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, MSPRC established various designated series to serve as units of the company to maintain various claims recovery assignments separate from other company assets, and to account for and associate certain assets with certain particular series.

21. MSPRC has enumerated rights relating to its designated series under its Amended and Restated Limited Liability Company Operating Agreement and consistent with Delaware

law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c).

22. Specifically, all rights and benefits arising from assignments to its series (including the assignments discussed below) belong to MSPRC. MSPRC is authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series under its Amended and Restated Limited Liability Company Operating Agreement. MSPRC retained the legal right to sue on behalf of each designated series and pursue all rights, benefits, or causes of action arising from assignments to a series in its own name or in the name of the designated series. Certain Medicare Advantage plans and healthcare benefit providers have assigned their recovery rights to assert the claims alleged in this Complaint to series of MSPRC. As such, MSPRC has the right and power to sue Defendant to recover the payments at issue in this action.

23. Certain series of Plaintiffs have executed irrevocable assignments of any and all rights to recover payments made on behalf of their assigner's health plan members and enrollees. These assignments authorize the series and, in turn, Plaintiffs through their Amended and Restated Limited Liability Company Operating Agreements, to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits. For purposes of giving examples, and only to serve to further demonstrate standing, Plaintiffs allege a few of the assignments below.

24. On May 30, 2019, Blue Cross & Blue Shield of Rhode Island ("BCBSRI") entered into a Statement of Work and Claims Purchase Agreement & Assignment with MSP Recovery, LLC, whereby it irrevocably assigned to MSP Recovery, LLC, all of its rights and claims to recovery against any liable entity (including Defendant) for payments made on behalf of its enrollees under Medicare Parts A, B, and D (the "BCBSRI Assignment"). The BCBSRI

Assignment specifically states:

> Client irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to (i) all Claims for which it has sent claims data to MSP Recovery, LLC, whether based in contract, tort or statutory right, and all related to recovery rights arising from and related all claims data transferred to MSP Recovery, LLC, and (ii) any and all causes of action, claims and demands of whatsoever nature relating to payments for healthcare services provided to Client's members and enrollees, and related legal or equitable rights (including, but not limited to, subrogation) to pursue and/or recover monies related to the Claims that Client had, may have had, or has asserted against any party in connection with the Claims and (iii) all causes of action, claims, rights and demands of whatsoever nature, legal or equitable, against primary payers, Responsible Parties and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws (all of the Claims and rights set forth in (i)-(iii), the "*Assigned Claims*").

25. Thereafter, effective on June 10, 2019, MSP Recovery, LLC, irrevocably assigned all rights acquired under the BCBSRI Assignment to Series 16-05-461, a designated series of MSP Recovery Claims, Series LLC (the "Series Assignment"). The Series Assignment from MSP Recovery, LLC to Series 16-05-461 states:

> The Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the "Claims" and "Assigned Claims", and all proceeds and products thereof (collectively the "*Assigned Claims*") as such terms are defined in the *Recovery Agreement*. This Assignment includes all the Assigned Claims irrespective of when the claims were vested in *BCBS Rhode Island*, inclusive of any and all claim(s), causes of actions, proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/or third parties that may be liable to *BCBS Rhode Island* arising from or relating to the Claims and all information relating thereto.

26. The BCBSRI Assignment contemplated that the Parties would enter into a "stand-alone assignment document evidencing" the BCBSRI Assignment. Following the contemplated due diligence period, the stand-alone assignment became effective May 30, 2019, thereby

approving and consenting to the Series Assignment and all rights contained therein, including all claims and reimbursement rights, to and in favor of MSPRC or any of its designated series, including but not limited to, Series 16-05-461.

27. Further, on October 22, 2020, Series 16-05-461 entered into an assignment agreement with Series 44-20-461, a designated series of Series 44, whereby it irrevocably assigned all rights it acquired through its assignment agreement with MSP Recovery, LLC. The assignment specifically states:

> [Series 16-05-461] . . . hereby irrevocably assigns, transfers, conveys, sets over, and delivers to [Series 44-20-461] and its successors and assigns, (i) any and all of Assignor's right, title, ownership, and interest in and to that Agreement, as well as (ii) the "Claims" and "Assigned Claims", and all proceeds and products thereof (collectively the "Assigned Claims") as such terms are defined in the Agreement.
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> This Assignment includes all the Assigned Claims irrespective of when the claims were vested in BCBSRI, inclusive of any and all claim(s), causes of actions, proceeds, products, and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/or third parties that may be liable to BCBSRI arising from or relating to the Claims and all information relating thereto.

28. Effective April 28, 2016, Health First Health Plans, Inc. ("HFHP"), a Medicare Advantage organization, irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendant) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to MSP Recovery, LLC (the "HFHP Assignment"). The HFHP Assignment expressly provides, in pertinent part:

> Client hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and

> all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto . . . all of which shall constitute the "Assigned Claims."
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> …
>
> The transfer, grant, right, or assignment of any and all of Client's right, title, ownership, interest and entitlements in and to the Assigned Claims shall remain the confidential and exclusive property of MSP Recovery or its assigns. This assignment is irrevocable and absolute.

29. On June 12, 2017, MSP Recovery, LLC, assigned all rights acquired under the HFHP Assignment to Series 16-05-456, a designated series of MSPRC (the "Series Assignment"). The Series Assignment states:

> [T]he undersigned Assignor . . . irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the Claims and Assigned Claims, (and all proceeds and products thereof, including any related assigned assets and assigned documents) as such terms are defined or contained in that certain (1) Assignment and (2) Addendum to the Recovery Agreement and Assignment Addendum, both given and effective April 28, 2016 and executed on June 1, 2018, by and between Health First Health Plans, Inc., a Florida corporation and Medicare Advantage Organization and party to contract number H1099 with The Centers for Medicare & Medicaid Services, as the "Client" and health plan assignor, and [MSP Recovery], a Florida limited liability company (the "Assignment"); irrespective of when the claims were vested in Client, inclusive of any and all claim(s), causes of actions, proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party pursuant to the Assignment from the Client, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims and all information relating thereto.

30. Further, on October 22, 2020, Series 16-05-456 entered into an assignment agreement with Series 44-20-456, a designated series of Series 44, whereby it irrevocably assigned all rights it acquired through its assignment agreement with MSP Recovery, LLC. The assignment specifically states:

> [Series 16-05-456] . . . hereby irrevocably assigns, transfers, conveys, sets over, and delivers to [Series 44-20-456] and its successors and assigns, (i) any and all of Assignor's right, title, ownership, and interest in and to the [claims], as well as (ii) the "Claims" and "Assigned Claims", and all proceeds and products thereof (collectively the "Assigned Claims") as such terms are defined in the Agreements.
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> This Assignment includes all the Assigned Claims irrespective of when the claims were vested in HFHP, inclusive of any and all claim(s), causes of actions, proceeds, products, and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/or third parties that may be liable to HFHP arising from or relating to the Claims and all information relating thereto.

31. On March 20, 2018, Group Health Incorporated and Health Insurance Plan of Greater New York (otherwise known as "EmblemHealth" or "Emblem") irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendant) for payments made on behalf of their enrollees under Medicare Parts A, B, and D to Series 16-08-483, a designated series of MSPRC (the "Emblem Assignments"). The Emblem Assignments specifically state:

> Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

32. On May 12, 2017, Summacare, Inc., irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to MSP Recovery, LLC (the "Summacare Assignment"). The Summacare Assignment specifically states:

> [Summacare] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of [Summacare's] right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [Summacare] that [Summacare] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to [Summacare] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".

33. On June 12, 2017, MSP Recovery, LLC, irrevocably assigned all rights acquired under the Summacare Assignment to Series 16-11-509, a designated series of MSPRC:

> [Assignor] irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the [claims] (and all proceeds and products thereof) as such terms are defined in the Recovery Agreement dated May 12, 2017, by and among [Summacare] . . . and [MSP Recovery] . . . .

Summacare consented to, acknowledged, approved, and ratified the assignment from MSP Recovery, LLC to Series 16-11-509, which is memorialized in a letter dated September 5, 2018.

34. On March 20, 2018, Connecticare, Inc., irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to Series 15-09-157, a designated series of MSPRC (the "Connecticare Assignment"). The Connecticare Assignment specifically states:

> Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

35. Defendant has manufactured and distributed Chantix throughout the United

States, for which consumers made co-payments, and TPPs either paid or reimbursed. On information and belief, the Plaintiffs' payments include those payments for Defendant's VCDs, which were also manufactured, distributed, and sold during that same period.

36. For example, and only to further demonstrate standing, Plaintiffs allege some exemplar payments made by its assignors for the VCDs in the table below. In each instance, one of Plaintiffs' assignors received a request to reimburse a prescription drug on behalf of an enrollee for a particular date of service indicated below. The assignors paid the amounts indicated for contaminated, FDA-recalled lots of VCDs. To be clear, the table below does not demonstrate all of Plaintiffs' assignors' payments for VCDs, let alone all of Plaintiffs' damages.[5]

| Plaintiff Entity | Assignor | Assignor's Enrollee[6] | Date of Service | Amount Paid |
|---|---|---|---|---|
| Series 44 | BCBSRI | Patient A | 8/1/20 | $188.05 |
| Series 44 | HFHP | Patient B | 5/6/19 | $407.64 |
| MSPRC | Summacare | Patient C | 9/16/19 | $401.11 |
| MSPRC | Emblem | Patient D | 2/27/17 | $281.69 |
| MSPRC | Connecticare | Patient E | 3/8/16 | $193.55 |
| Series 44 | BCBSRI | Patient F | 10/20/17 | $398.63 |
| Series 44 | HFHP | Patient G | 1/25/16 | $292.30 |
| MSPRC | Summacare | Patient H | 1/28/16 | $373.99 |
| MSPRC | Emblem | Patient I | 8/30/16 | $342.45 |
| MSPRC | Connecticare | Patient J | 6/17/16 | $220.90 |

37. Defendant Pfizer is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017. Defendant Pfizer on its own or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Pfizer has been engaged in the manufacturing, sale,

[5] The representative payments in the table correspond to the FDA's list of recalled VCDs. The table does not list any payments made for VCDs whose contamination was not disclosed prior to the FDA's recall.

[6] To ensure that this complaint complies with federal law under the Health Insurance Portability and Accountability Act ("HIPAA"), the individual enrollees are referred to by these pseudonyms.

or distribution of Chantix and adulterated and misbranded VCDs in the United States.

## JURISDICTION AND VENUE

38. This Court has original jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendant, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

39. This Court has personal jurisdiction over Defendant under 28 U.S.C. § 1407, and because Defendant has sufficient minimum contacts in the State of Florida, and because Defendant has otherwise intentionally availed itself of the markets within the State of Florida through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

40. Venue is proper in this District because the claims alleged in this action accrued in this District and Defendant regularly transacts its affairs in this District.

41. Defendant is subject to the personal jurisdiction of this Court because the Defendant conducts business within the State of Florida, maintain and carry out continuous and systematic contacts within the State of Florida and this judicial District, regularly transact business within the State of Florida and this judicial District, and regularly avail themselves of the benefits of their presence in the State of Florida and this judicial District.

## FACTUAL ALLEGATIONS

### I. Background

#### *A. Prescription Drug Reimbursement*

42. The pharmaceutical supply chain in the United States consists of four major actors: pharmaceutical manufacturers, wholesale distributors, pharmacies, and Pharmacy Benefit

Managers ("PBMs").

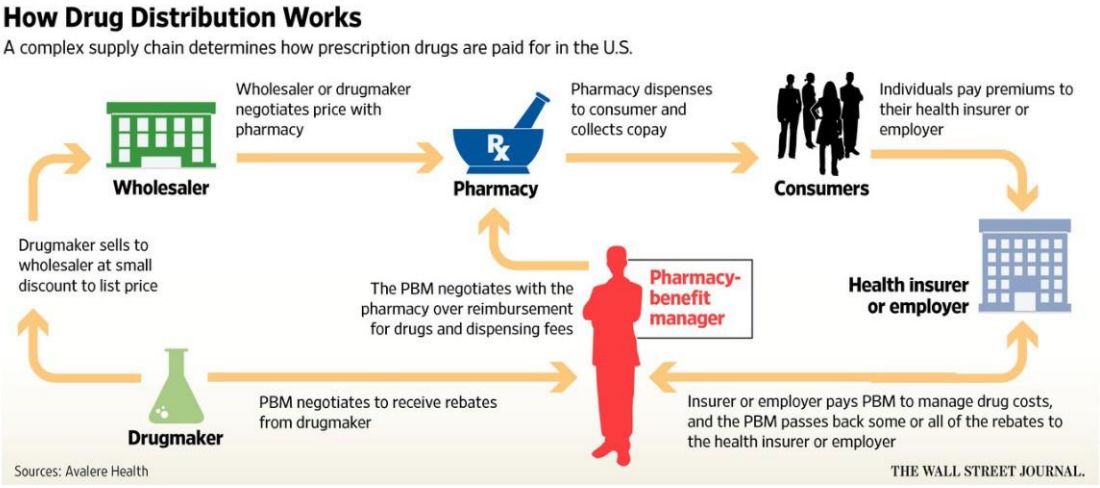
43. Pharmaceutical manufacturers produce drugs that they distribute to wholesale distributors, who further distribute to retail or mail-order pharmacies. Pharmacies dispense the prescription drugs to beneficiaries for consumption. Prescription drugs are processed through quality and utilization management screens by PBMs.

44. TPPs contract with and pay PBMs to administer their drug programs. PBMs, acting as agents for the TPPs, are tasked with developing drug formularies (the list of drugs included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies, and negotiating with pharmaceutical manufacturers. TPPs pay PBMs to control prescription drug costs. In some instances, PBMs are responsible for placing drugs, such as Chantix, on the TPPs' formularies.

45. In managing formularies, TPPs and their PBMs reasonably expect that branded prescription drugs reimbursable on their formularies are the same as the respective FDA-approved branded drugs. The TPPs permitted Chantix, and VCDs, to be included on their formularies based on the Defendant's misrepresentations that their VCDs were bioequivalent and the same as FDA-approved branded Chantix, complied with all current Good Manufacturing Practices ("cGMPs"), and were safe for consumption.

46. The formulary placement corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug—the higher the placement, the lower the co-payment, and the higher likelihood that plan beneficiaries will purchase the drug instead of a more expensive alternative. As a result, higher formulary placement increases the likelihood that a doctor will prescribe the drug. TPPs provide copies of their PBMs' formularies to providers, pharmacists, and patients in their network to aid prescribers' adherence to the formulary.

47. The following chart, published by the Wall Street Journal,[7] broadly illustrates the pharmaceutical supply chain:




48. When patients present their prescription at a pharmacy, the drug's placement on the TPP's formulary will determine the amount of the patient's co-payment. Once the patient's prescription is filled, the pharmacy submits a claim to the PBM for reimbursement. PBMs then accumulate those individual reimbursements and present them to TPPs for payment.

### *B. Prescription Drug Product Identification and Tracing*

49. For each approved product (whether brand or generic) the FDA issues a unique 10-digit code (the National Drug Code, or NDC) that follows the product from manufacturing through retail dispensing. The NDC embeds details about the specific product, including the identity of the manufacturer (or labeler), the strength, dosage form, and formulation of the drug, and the package size and type.[8]

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[7] Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*, WALL ST. J. (Oct. 3, 2016), https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336.

[8] *National Drug Code Directory*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm (last visited Oct. 19, 2021); *National Drug Codes Explained*, DRUGS.COM, https://www.drugs.com/ndc.html (last visited Oct. 19, 2021).

50. The NDC is a critical component of each and every transfer of a prescription drug (from the manufacturer to the wholesaler; from the wholesaler to the retailer; and from the retailer to the consumer) and, therefore, every transaction is accompanied by and labeled with the NDC. This same code is used by TPPs in the real-time claims adjudication process to identify the precise dollar amount they will reimburse the pharmacy for a particular prescription drug purchase.

51. Retail prescription labels display the NDC of the dispensed product, which is part of the electronic dispensing record. In many cases, the "lot" number will also appear on the prescription bottle provided to the consumer and, thus, specifically indicate whether the recall applies to the particular pills in the bottle.[9]

52. The lot number is also used to report issues arising around a particular drug. For example, lot numbers are used by pharmacists to report Adverse Events ("AE") (that is, patient-specific side effects or complications associated with the use of a prescription drug). This is an important part of drug safety monitoring in the United States and has led to recalls or relabeling of numerous drugs. Pharmacists make such reports using the FDA's MedWatch system using Form 3500.[10]

### *C. The Drug Supply Chain Security Act Requires Tracing of Product*

53. The Drug Supply Chain Security Act ("DSCSA")[11] was enacted in 2013, and requires prescription drug manufacturers, wholesalers, repackagers, and pharmacies to "[e]xchange information about a drug and who handled it each time it is sold in the U.S. market."

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[9] A lot number is an identification number tied to a particular lot of pills from a single manufacturer.

[10] *Instructions for Completing Form FDA 3500*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda- 3500#Section%20B:%20Adverse%20Event%20or%20Product%20Problem (last visited Oct. 19, 2021).

[11] 21 U.S.C. § 360eee.

54. The DSCSA was implemented as one part of the Drug Quality and Security Act ("DQSA"), aimed at addressing vulnerabilities in the drug supply chain, and facilitating tracing of certain prescription drugs in finished dosage form through the supply chain.[12]

55. While the DSCSA was enacted in 2013, participants in the pharmaceutical supply chain maintained similar information as a part of their ordinary course of business prior to the enactment of the DSCSA.

56. The DSCSA generally requires participants in the drug supply manufacturing chain (starting from the manufacturer, through the wholesaler, to the retail pharmacy) to retain, for every pharmaceutical drug transaction, the following information about that transaction: product name; National Drug Code; container size; number of containers; lot number; date of transaction; date of shipment; and name and address of the entity transferring ownership and taking ownership of the product.

57. The DSCSA requires that this data be kept in a manner to allow these authorized participants to respond within 48 hours to requests from appropriate federal or state officials—in the event of a recall or for the purpose of investigating suspect product or an illegitimate product—for the transaction history of the pharmaceutical product.[13]

58. The supply chain for distribution of prescription drugs in the U.S. is highly concentrated. This means that data obtained from a relatively small number of market participants can provide detailed information about the large majority of Chantix and VCD sales, transfers, and prescription fills.

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[12] Daniel R. Levinson, *Drug Supply Chain Security: Dispensers Received Most Tracing Information*, U.S. DEPT. HEALTH & HUM. SERVS. (March 2018), https://oig.hhs.gov/oei/reports/oei-05-16-00550.pdf, at p. 2.

[13] *Title II of the Drug Quality and Security Act*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act (last visited Oct. 19, 2021).

59. The entire process of reimbursing pharmacies and consumers for end-purchases depends on the ability to know the precise drug and packaging that was dispensed, as well as the manufacturer of that drug. This system has necessarily resulted in very high levels of data standardization in this industry. Although pharmacies maintain their own "pharmacy log" data reflecting dispensing, sales and return activity, the key elements are fundamentally similar.

60. Because pharmacies require similar information for their own tracking and inventory systems, and wholesalers sell to multiple pharmacy chains, the key elements are fundamentally the same.

61. Further, all pharmacies must use the basic data fields, definitions and formats provided in the Telecommunications Guidelines developed by the National Council for Prescription Drug Programs, the use of which was made mandatory in 2003 under regulations implementing the Health Insurance Portability and Accountability Act (HIPAA).[14] Because of these HIPAA requirements, all of these inter-related systems (Manufacturers, Wholesalers, Retailers, and TPPs) use a common language to identify products.

62. As a general matter, for Medicare and Medicaid compliance, pharmacies typically keep prescription records for ten years.[15]

63. A key part of the DSCSA is the requirement that "product tracing information should be exchanged" for each transaction and retained for at least six years,[16] including the following transaction information ("TI"):[17]

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[14] *Pharmacy: A Prescription for Improving the Healthcare System,* NAT'L COUNSEL FOR PRESCRIPTION DRUG PROGRAMS (Oct. 2009), https://www.ncpdp.org/NCPDP/media/pdf/wp/RxforImprovingHealthcare.pdf, at p. 14.

[15] 42 C.F.R. § 423.505(d).

[16] *Protect Your Patients,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/113114/download (last visited Oct. 19, 2021); 21 U.S.C.§§ 360eee-1(b)(1)(A)(ii), (c)(bb)(BB)(II)(v)(I), and (d)(1)(A)(iii).

[17] *Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Overview of*

- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code (NDC) number of the product
- Container size
- Number of containers
- Lot number of the product
- Date of the transaction
- Date of the shipment, if more than 24 hours after the date of the transaction
- Business name and address of the person from whom and to whom ownership is being transferred

64. For example, the DSCSA also mandates use of a composite "product identifier" that Defendant was required to begin applying to prescription drug packages and cases.[18]

65. The term "product identifier" "means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier . . . the standardized numerical identifier, lot number, and expiration date of the product."[19]

66. Publicly available Guidelines published by AmerisourceBergen require that "each Prescription Drug lowest saleable unit" it receives from a manufacturer must have the clearly indicated product identifier on the unit label.[20] In addition, case labels, and partial case labels must list the lot number and expiration date.[21] The Guidelines illustrate these requirements as reproduced below.

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*Product TracingRequirements*, U.S. FOOD & DRUG ADMIN. (Sept. 2015), https://www.fda.gov/media/93779/download, at pp. 8-9.

[18] *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry*, U.S. FOOD & DRUG ADMIN. (Sept. 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-identifier-requirements-under-drug-supply-chain-security-act-compliance-policy-guidance.

[19] 21 U.S.C. § 360eee(14).

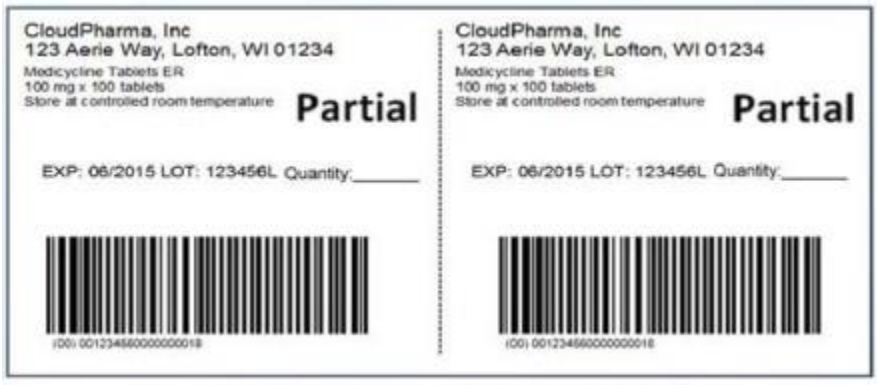
[20] *AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide*, AMERISOURCEBERGEN, https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer- logistics-guideline-final-v14.pdf?la=en&hash=5297B4C716DBBE9A956F31CD2B194BD165F97465 at p. 14 (last visited Oct. 19, 2021).

[21] *Id.* at pp. 15-16.

***AmerisourceBergen Manufacturer Labeling Requirements***[22]


DSCSA RX Serialized Unit Label


Example of Rx Serialized Homogenous Case Label




Example Partial Case Labeled with SSCC

### *D. The Drug Approval Framework*

67. Brand drug companies submitting a New Drug Application ("NDA") must demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et*

[22] *Id.* at 14-16.

*seq.*

68. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new drug for sale and marketing in the United States.

69. An NDA is supposed to provide enough information to permit the FDA to decide (i) whether the drug is safe and effective for its proposed uses and whether the benefits of the drug outweigh the risks; (ii) whether the drug's proposed labeling is appropriate and what it should contain; and (iii) whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.[23]

70. As the FDA puts it, the submitted NDA documentation "is supposed to tell the drug's whole story," including "what the ingredients of the drug are."[24]

71. If a branded drug manufacturer ceases to manufacture a drug that meets all terms of its NDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

72. If a branded drug manufacturer ceases to manufacture a drug that meets all terms of its NDA approval, or, in other words, when the drug is not the same as its corresponding brand-name drug, the manufacturer may no longer rely on the drug's labeling.

### *E. Approval of the NDA for Chantix*

73. Chantix is known generically as varenicline (as the tartrate salt), and is a partial nicotine agonist. It is a first-line therapy in the treatment to aid in smoking cessation. At a very high level, the drug works by interfering with the nicotine receptors in the human brain. This has

[23] *See, e.g.*, *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN. (June 10, 2019), https://www.fda.gov/drugs/types-applications/new-drug-application-nda.
[24] *Id.*

the effect of lessening the pleasure a person gets from smoking, or lessening the craving to smoke.

74. The FDA approved Chantix in May 2006. Pfizer later succeeded in extending its patent exclusivity for Chantix through August 2022, meaning Chantix has not faced generic drug competition since its launch.

75. Chantix's FDA-approved labeling specifies the active and inactive ingredients. Neither N-nitroso-varenicline nor NDMA nor any other nitrosamine is listed among the FDA-approved ingredients nor are any of these contaminants FDA-approved ingredients of Chantix.

### *F. Drugs Must Be Manufactured in Compliance with Good Manufacturing Practices*

76. Under federal law, pharmaceutical drugs must be manufactured in accordance with cGMPs to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

77. Moreover, 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

78. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards for: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory

controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

79. Under federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring the continuing quality of the subcontractors' operations.

80. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibilityand authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review productionrecords to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by anothercompany. 21 C.F.R. § 211.22(a).

81. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

82. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

83. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

***G. Adulterated or Misbranded Drugs Are Illegal to Sell***

84. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

85. Among the ways a drug may be adulterated or misbranded are:

a. "if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health";[25]

b. "if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements . . . as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess";[26]

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and . . . its quality or purity falls

[25] 21 U.S.C. § 351(a)(2)(A).
[26] 21 U.S.C. § 351(a)(2)(B).

below, the standard set forth in such compendium";[27] or

d. "If . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[28]

86. A drug is misbranded:

a. "If its labeling is false or misleading in any particular";[29]

b. "If any word, statement, or other information required . . . to appear onthe label or labeling is not prominently placed thereon . . . in such terms as torender it likely to be read and understood by the ordinary individual under customary conditions of purchase and use";[30]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient";[31]

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings . . . against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users";[32]

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein";[33]

f. "if it is an imitation of another drug";[34]

[27] 21 U.S.C. § 351(b).
[28] 21 U.S.C. § 351(d).
[29] 21 U.S.C. § 352(a)(1).
[30] 21 U.S.C. § 352(c).
[31] 21 U.S.C. § 352(e)(1)(A)(ii).
[32] 21 U.S.C. § 352(f).
[33] 21 U.S.C. § 352(g).
[34] 21 U.S.C. § 352(i)(2).

g. "if it is offered for sale under the name of another drug;"[35]

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof";[36]

i. If the drug is advertised incorrectly in any manner;[37] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation."[38]

87. The manufacture and sale of any adulterated or misbranded drug is prohibited under federal law.[39]

88. The introduction into commerce of any adulterated or misbranded drug is also prohibited.[40]

89. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[41]

90. Defendant's contaminated, unapproved VCDs were adulterated or misbranded, or both, for the reasons demonstrated above.

91. Plaintiffs reference federal law in this Complaint, not in any attempt to enforce it, but to demonstrate that its state-law tort claims do not impose any additional obligations on Defendant, beyond what is already required of it under federal law.

[35] 21 U.S.C. § 352(i)(3).
[36] 21 U.S.C. § 352(j).
[37] 21 U.S.C. § 352(n).
[38] 21 U.S.C. § 352(p).
[39] 21 U.S.C. § 331(g).
[40] 21 U.S.C. § 331(a).
[41] 21 U.S.C. § 331(c).

## II. The Drugs Purchased by Plaintiffs' Assignors Were Not Chantix, But Adulterated and Misbranded Varenicline-Containing Drugs, Not of the Same Quality

92. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[42]

93. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."[43]

94. Accordingly, the FDA requires the submission of an NDA by manufacturers whenever a new active ingredient is added to a drug, as the drug has become a new and differing drug from those previously approved by the FDA. Absent such an application, followed by a review and approval by the FDA, the new drug remains a distinct, unapproved product.[44]

95. This new and unapproved drug with additional active ingredients (such as

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[42] *Human Drugs*, U.S. FOOD & DRUG ADMIN. (Mar. 5, 2021), https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.

[43] 21 C.F.R. § 210.3(b)(7).

[44] *See* 21 C.F.R. § 310.3(h).

nitrosamines) cannot have the same label as the brand-name drug, as the two products are no longer the same.

96. At the very least and alternatively, drugs with differing and dangerous ingredients than brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.[45]

97. Here, N-nitroso-varenicline and other nitrosamines resulted from the deficient manufacturing process of the VCDs, rendering the VCDs different than the FDA-approved version of Chantix. Importantly, N-nitroso-varenicline and other nitrosamines can cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the human body, and thus, N-nitroso-varenicline and other nitrosamines are, by definition, an active ingredient in a drug.

98. Because the VCDs purchased by Plaintiffs' assignors, and ultimately ingested by their beneficiaries, were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

99. The presence of additional active ingredients (N-nitroso-varenicline and other nitrosamines) and potentially other deviations from Defendant's NDA rendered Defendant's VCDs of a lesser quality than FDA-approved Chantix.

## III. Defendant Made False Statements in the Labeling

100. A manufacturer must give adequate directions for the use of a pharmaceutical drug so that a "layman can use a drug safely and for the purposes for which it is intended,"[46] and

[45] *See generally Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA*, U.S. DEP'T JUST. (May 13, 2013), https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.

[46] 21 C.F.R. § 201.5.

conform to requirements governing the appearance of the label.[47]

101. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[48] and therefore broadly includes nearly every form of promotional activity, including not only "package inserts" but also advertising.

102. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[49]

103. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[50]

104. Because Defendant did not disclose that its product contained N-nitroso-varenicline or other nitrosamines as an ingredient, the subject drugs were misbranded.

105. In addition, by referring to its drugs as "Chantix," Defendant was making false statements.

106. It is unlawful to introduce a misbranded drug into interstate commerce.[51] Thus, the Chantix products ingested consumers (and paid for or reimbursed by TPPs, including Plaintiffs' assignors) were unlawfully distributed and sold.

## IV. Defendant Represented VCDs were Manufactured in Compliance with Current Good Manufacturing Practices

107. Under federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug

[47] 21 C.F.R. § 801.15.
[48] *See id.*
[49] *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[50] 21 C.F.R. §§ 201.6; 201.10.
[51] 21 U.S.C. § 331(a).

products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring the continuing quality of the subcontractors' operations.

108. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

109. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

110. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

111. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

112. Defendant's VCDs did not conform with the NDA specifications, which demonstrates inadequate production, process, and quality oversight by Defendant.

## V. Defendant's Actions Resulted in Contaminated, Adulterated and Misbranded VCDs

113. On October 26, 2020, Health Canada, the FDA analogue for Canada, sent a letter to Apotex, Inc., concerning risk of the presence of nitrosamine impurities in drugs.

114. Apotex distributed Chantix in Canada on Defendant's behalf.

115. Health Canada informed Apotex that it had been informed by other global regulators "of the presence of new nitrosamine impurities in varenicline API [active pharmaceutical ingredient]: 7,8-dinitro-1,2,4,5-tetrahydro-3H-1,5-methanobenzo[d]azepin-N-nitrosamine,1-(7,8-diamino-1,2,4,5-tetrahydro-3H-1,5-methanobenzo[o'1azepin-3-yl)-N-nitrosamine and N- nitroso varenicline."

116. Health Canada continued: "After a preliminary internal review conducted by Health Canada, it was concluded that there is risk for formation of these new nitrosamines impurities for all MAHs of varenicline drug products in Canada. Additional risks for other nitrosamines (e.g. NOMA, N-nitrosodiethylamine (NOEA)) might exist if nitrocellulose is being used as a component of the blister packaging for varenicline products."

117. N-nitrosodimethylamine, commonly known as NDMA, is an odorless, yellow liquid.[52]

118. According to the U.S. Environmental Protection Agency, "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[53]

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[52] *Toxicological Profile for N-Nitrosodimethylamine*, U.S. ENVIRONMENTAL PROT. AGENCY (Dec. 1989), https://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

[53] *Technical Fact Sheet (NDMA)*, U.S. ENVIRONMENTAL PROT. AGENCY (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

119. NDMA can be unintentionally produced in and released from industrial sources through chemical reactions involving other chemicals called alkylamines.

120. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[54]

121. The U.S. Department of Health and Human Services ("DHHS") similarly states that NDMA is reasonably anticipated to be a human carcinogen.[55] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[56]

122. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."[57]

123. WHO and IARC classify NDMA as one of sixty-six agents that are "probably carcinogenic to humans" (Classification 2A).

124. Anecdotally, NDMA has also been used in intentional poisonings.[58]

125. Other nitrosamines with similar or even more severe carcinogenic risk profiles include N-nitrosodiethlamine ("NDEA"), as well as N-nitroso-varenicline.

126. Nitrosamines are considered genotoxic compounds, as it contains nitroso groups,

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[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Supra* n. 52 at p. 2.
[58] *See* Chase Purde, *A common blood-pressure medicine is being recalled because of a toxic ingredient*, QUARTZ (July 18, 2018), https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/.

which are gene-mutating groups.[59]

127. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005, or earlier.[60]

128. In late June 2021, Defendant recalled certain lots of VCDs because of the presence of N-nitroso-varenicline and/or other nitrosamines.

129. A couple of weeks later, on July 19, 2021, Defendant announced a wider recall of additional VCDs due to N-nitroso-varenicline or other nitrosamine contamination.

130. The recalls were due to the presence of N-nitroso-varenicline above established acceptable daily intake levels. The precise levels were not disclosed.

131. On September 16, 2021, Defendant expanded its recall to include all lots of VCDs "due to the presence of a nitrosamine[.]"[61]

## VI. Defendant Had Actual or Constructive Notice of Nitrosamine Contamination of Its Adulterated, Misbranded, or Unapproved VCDs

132. Neither N-nitroso-varenicline nor other nitrosamines are FDA-approved ingredients of Chantix. Moreover, none of Defendant's VCDs identify N-nitroso-varenicline or other nitrosamines as an ingredient on the products' labels or elsewhere. This is because these nitrosamines are probable human carcinogens and are not approved to be included in the active pharmaceutical ingredient ("API") or finished-dose product. Their inclusion in Defendant's VCDs renders the VCDs adulterated and misbranded compared to Defendant's warranties and

[59] Ketan Agravat, *Nitroso Impurities In Valsartan: How Did We Miss Them?*, PHARM. ONLINE (Oct. 30, 2018), https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.

[60] Lutz Muller et al., *A rationale for determining, testing, and controlling specific impurities in pharmaceuticals that possess potential for genotoxicity*, REGUL. TOXICOLOGY & PHARMACOLOGY (Dec. 26, 2005), http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.

[61] *See supra* n. 4.

representations.

133. If Defendant had not routinely disregarded the FDA's cGMPs, or had fulfilled its quality assurance obligations, Defendant would have identified the presence of these nitrosamine contaminants almost immediately.

134. This is certainly true since at least 2018, when many manufacturers of valsartan, losartan, and irbesartan instituted massive waves of recalls due to nitrosamine contamination. That knowledge alone should have informed Defendant to check its VCDs for nitrosamines then, if not sooner.

135. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods. 21 C.F.R. § 211.110(c).

136. And, as shown above, Defendant's quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer.

137. Also, as shown above, the quality control units for all of Defendant's manufacturing were grossly deficient in fulfilling their responsibilities.

138. If these sampling-related and quality-control-related cGMPs were properly observed by Defendant, the nitrosamine contamination in Defendant's VCDs would have been discovered almost immediately, and Defendant was thus (at minimum) on constructive notice from the moment its VCDs became contaminated.

139. However, there are indications that Defendant had actual knowledge of its VCDs'

contamination, and certainly not later than Health Canada's communication to Apotex in 2020.

140. And yet, Defendant knowingly, recklessly, or negligently introduced adulterated or misbranded VCDs containing dangerous amounts of nitrosamines into the U.S.market. Defendant failed to recall its VCDs because they feared permanently ceding market share to competitors.

## VII. Defendant's Warranties and Fraudulent and Deceptive Statements to TPPs Regarding Its VCDs

141. Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to TPPs about its adulterated or misbranded VCDs.

142. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" known as the Orange Book.[62] The Orange Book is a public document; Defendant sought and received the inclusion of its VCD products in the Orange Book upon approval of its NDAs.

143. Defendant's VCDs are accompanied by an FDA-approved label. By presenting TPPs with an FDA-approved VCD label, Defendant made representations and express or implied warranties of the "sameness" of its product to the Orange Book listed Chantix, and that its products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels or were not adulterated or misbranded or misbranded.

144. By introducing its VCDs into the United States marketed as "Chantix," Defendant represent and warrant to TPPs that its VCDs are in fact the same as Chantix. Much of the drug supply chain, including the most critical components of that supply chain (for example, patients and TPPs) rely on these representations and warranties.

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[62] *Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN. (Aug. 13, 2021), https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

145. In addition, Defendant affirmatively misrepresented and warranted to TPPs through its websites, brochures, and other marketing or informational materials that its VCDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

146. The presence of nitrosamines in Defendant's VCDs: (1) renders Defendant's VCDs non-bioequivalent (that is, not the same) to listed Chantix, thus breaching Defendant's express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendant's VCDs worthless, thus breaching Defendant's express warranties of sameness; and (3) results in Defendant's VCDs containing an ingredient that is not also contained in the FDA-approved label, also breaching Defendant's express warranty of sameness (and express warranty that the products contained the ingredients listed on Defendant's FDA-approved label). Defendant willfully, recklessly, or negligently failed to ensure its VCDs' labels and other advertising or marketing statements accurately conveyed information about its products.

147. The presence of nitrosamines in Defendant's VCDs and serial and willful failures to comply with cGMPs and other shortcomings in Defendant's drug manufacturing processes have resulted in Defendant's VCDs being adulterated or misbranded.

148. At all relevant times, Defendant also impliedly warranted that its VCDs were merchantable and fit for their ordinary purposes.

149. Naturally, due to their status as probable human carcinogens as listed by both the IARC and the U.S. EPA, nitrosamines including NDMA are not FDA-approved ingredients in VCDs. The presence of NDMA and other similar nitrosamines or impurities in Defendant's VCDs means that Defendant has violated implied warranties to Plaintiffs and Class Members. The presence of NDMA and other nitrosamines in Defendant's VCDs makes Defendant's VCDs

non-merchantable and not fit for its ordinary purposes, breaching Defendant's implied warranty of merchantability and/or fitness for ordinary purposes.

150. For these and other reasons, Defendant's VCDs are, therefore, adulterated, misbranded, or unapproved, and it was illegal for Defendant to have introduced or sold such VCDs in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

151. Adulterated, misbranded, or unapproved VCDs contaminated with cancer-causing compounds are essentially worthless. No reasonable TPP (including Plaintiffs' assignors) would purchase (or reimburse) these nitrosamine-laden VCDs. Nor could they. As an adulterated, misbranded, or unapproved VCDs cannot be legally sold or purchased within the United States. At a minimum, adulterated, misbranded, or unapproved VCDs were worth less than their non-contaminated equivalents. Further, adulterated, misbranded, and/or unapproved VCDs do not possess the same safety and efficacy profiles as their branded equivalents. As such, the VCDs were not what they were supposed to be.

152. Because of the seriousness of the impurity—unsafe levels of a carcinogen—all or virtually all TPPs immediately stopped paying for the tainted drug products after receiving notice of the recall. The TPPs paid for reimbursed payments for a safe alternative. VCDs had no use or value and were thus discarded.

## VIII. Fraudulent Concealment and Tolling

153. Plaintiffs' and Class Members' causes of action accrued on the date the FDA announced the recall of Defendant's VCDs.

154. Alternatively, any statute of limitation or prescriptive period is equitably tolled on because of fraudulent concealment. Defendant affirmatively concealed from Plaintiffs and other Class Members its unlawful conduct. Defendant affirmatively strove to avoid disclosing their knowledge of its cGMP violations with related to their VCDs, and of the fact that their VCDs were

adulterated and/or misbranded and contaminated with nitrosamines, and were not the same as the FDA-approved Chantix.

155. For instance, Defendant did not reveal to the public that its VCDs contained nitrosamines or was otherwise adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to FDA-approved Chantix.

156. To the contrary, Defendant continued to represent and warrant that its VCDs were actually "Chantix" when they were not the same as Chantix.

157. Because of this, Plaintiffs and other Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendant's false and misleading explanations, or obfuscations, lulled Plaintiffs and Class Members into believing that the prices paid for Defendant's VCDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

158. As a result of Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs and other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

## IX. CLASS ACTION ALLEGATIONS

159. Plaintiffs seek to represent a Nationwide Class under Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) as defined below:

**National Class:** All entities in the United States and its

territories and possessions who paid any amount of money for a varenicline-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Defendant.

**Florida Subclass:** All entities in Florida and its territories and possessions who paid any amount of money for a varenicline-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Defendant.

160. Plaintiffs allege additional sub-classes for all TPPs in each State, territory, or possession—or combinations of States, territories, or possessions to the extent class members from these jurisdictions can be grouped together for purposes of class treatment—that paid any amount of money out of pocket for a varenicline-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Defendant (collectively, the "Subclasses").

161. Collectively, the foregoing Nationwide Class and the Subclasses are referred to as the "Class."

162. Excluded from the Class are: (a) any judge or magistrate presiding over this action, and members of their families; (b) Defendant and affiliated entities, and their employees, officers, directors, and agents; (c) Defendant's legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

163. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or to create or modify subclasses as the Court deems necessary.

164. Plaintiffs meet the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

165. **Numerosity**: While the exact number of Class Members cannot be determined

without discovery, they are believed to consist of potentially hundreds of entities nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

166. **Existence and predominance of common questions of law and fact:** Common questions of law and fact exist as to all Class and Subclass Members and predominate over any questions affecting on individual Class and Subclass members. These common legal and factual questions include, but are not limited to, the following:

a. Whether Defendant made express or implied warranties of "sameness" to Plaintiffs and Class Members regarding its VCDs;

b. Whether Defendant's VCDs were, in fact, the same as Chantix consistent with such express or implied warranties;

c. Whether Defendant's VCDs were contaminated with nitrosamines or similar contaminants;

d. Whether Defendant's VCDs containing nitrosamines or similar contaminants were adulterated or misbranded;

e. Whether Defendant violated cGMPs regarding the manufacture of its VCDs;

f. Whether Defendant falsely claimed that its VCDs were the same as Chantix and thus therapeutically interchangeable;

g. Whether Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs;

h. Whether Plaintiffs and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of their damages;

i. Whether a common damages model can calculate damages on a class-wide basis;

j. When Plaintiffs' and Class Members' causes of action accrued; and

k. Whether Defendant fraudulently concealed Plaintiffs' and Class Members' causes of action.

167. **Typicality**: Plaintiffs' claims are typical of Class Members' claims. Plaintiffs and Class Members all suffered the same type of economic harm. Plaintiffs have substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as the claims of all other Class Members.

168. **Adequacy of Representation**: Plaintiffs are committed to pursuing this action and have retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiffs and their counsel will fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiffs have no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

169. The elements of Rule 23(b)(2) are met. Defendant has acted on grounds that apply generally to Class Members so that preliminary or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

170. **Superiority:** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. Although many other Class Members have claims against Defendant, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition,

individualized rulings and judgments could result in inconsistent relief for similarly situated plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

**FIRST COUNT**
**BREACH OF EXPRESS WARRANTIES**

171. Plaintiffs re-allege and incorporate the paragraphs 1 to 157 as if fully set forth here.

172. Plaintiffs, and each member of the Class, formed a contract with Defendant at the time Plaintiffs and the other Class Members purchased the VCDs. The terms of the contract include the promises and affirmations of fact made by Defendant on the VCDs' packaging and through marketing and advertising, including that the product would be bioequivalent to and the same as the name-brand medication Chantix, and would be of same "quality" and have the same safety and efficacy profile as branded Chantix. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiffs and the members of the Class and Defendant.

173. Defendant expressly warranted that its VCDs were fit for its ordinary use as an FDA-approved pharmaceutical that is therapeutically equivalent to and the same as branded Chantix. In other words, Defendant expressly warranted that its products were the same as branded Chantix.

174. Defendant sold VCDs that they expressly warranted were compliant with cGMP and not adulterated or misbranded.

175. Defendant's VCDs did not conform to Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and was

adulterated and misbranded.

176. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C.Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313;Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont.Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A §2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313; and Wyo. Stat. § 34.1-2-313.

177. At the time that Defendant marketed and sold its VCDs, it recognized the purposes for which the products would be used, and expressly warranted the products were the same as branded Chantix, and cGMP compliant and not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs

and other Class Members including but not limited to express representations made in referring to its VCDs.

178. Defendant breached its express warranties with respect to its VCDs as they were not of merchantable quality, were not fit for their ordinary purpose, and did not comply with cGMP and was adulterated and misbranded.

179. Plaintiffs and each member of the Class would not have purchased the VCDs had they known these drugs were not the same as branded Chantix, did not contain the same ingredients, did not have the same safety and efficacy profile of branded Chantix, and contained NDMA.

180. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases, in that the VCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

**SECOND COUNT**
**BREACH OF IMPLIED WARRANTIES**

181. Plaintiffs re-allege and incorporate paragraphs 1 to 157 as if fully set forth here.

182. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2- 314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat.

Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314; and Wyo. Stat. § 34.1-2-314.

183. Defendant was a merchant within the meaning of the above statutes.

184. Defendant's VCDs constituted "goods" or the equivalent within the meaning of the above statutes.

185. Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit VCDs for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendant are involved such that the product was of fit and merchantable quality.

186. Defendant knew or should have known that its VCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to branded Chantix (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that its VCDs were of merchantable quality and fit for that purpose.

187. Defendant breached its implied warranty because Defendant's VCDs were not of

merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

188. Plaintiffs and other Class members purchased the VCDs in reliance on Defendant's skill and judgment and the implied warranties of fitness for the purpose.

189. The VCDs were not altered by Plaintiffs or Class members.

190. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendant's VCDs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

**THIRD COUNT**
**MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.***

191. Plaintiffs re-allege and incorporate paragraphs 1 to 157 as if fully set forth here.

192. Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

193. Plaintiffs and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

194. Defendant expressly or impliedly warranted its VCDs as alleged in the First and Second Causes of Action.

195. Under 15 U.S.C. § 2310(d)(1), Plaintiffs and Other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiffs sue pursuant to this section to recover money damages and for legal and equitable

relief on behalf of itself and the Class Members.

196. Defendant has not acted on the opportunity to cure its failure with respected to its warranted VCDs.

197. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

**FOURTH COUNT**
**FRAUD**

198. Plaintiffs re-allege and incorporate paragraphs 1 to 157 as if fully set forth here.

199. Defendant affirmatively misrepresented material facts including, among other things, that its VCDs were therapeutically equivalent and the same as its branded Chantix or complied with cGMPs or were not adulterated or misbranded.

200. Defendant omitted material facts including, among other things, that its VCDs were not therapeutically equivalent or the same as branded Chantix and did not comply with cGMPs or were adulterated, misbranded, or unapproved.

201. Defendant's actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendant's VCDs—products which Defendant knew or should have known were not therapeutically equivalent to or the same as branded Chantix or did not comply with cGMPs or were adulterated or misbranded. Plaintiffs and other Class Members would not have purchased Defendant's VCDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendant's VCDs had they known the truth because Defendant's VCDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on Defendant's fraudulent misrepresentations and omissions.

202. Defendant knew, or reasonably should have known, that its misrepresentations

were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

203. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendant's VCDs.

204. Defendant's misrepresentations and omissions were material.

205. Defendant actively concealed its misrepresentations and omissions from the Class, government regulators, and the public.

206. To the extent applicable, Defendant intended its misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendant's VCDs.

207. But for these misrepresentations and omissions, Plaintiffs and other Class Members would not have paid for Defendant's VCDs.

208. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendant's misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class member, including through product labeling and other statements by Defendant. No reasonable consumer would have paid what they did for Defendant's VCDs but for Defendant's unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

209. Plaintiffs and other Class Members were damaged by reason of Defendant's misrepresentations and omissions as alleged here.

## FIFTH COUNT
## NEGLIGENT MISREPRESENTATION AND OMISSION

210. Plaintiffs re-allege and incorporate paragraphs 1 to 157 as if fully set forth here.

211. Defendant had or undertook a duty to represent to the quality, nature, and characteristics of its VCDs accurately and truthfully.

212. Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its VCDs.

213. Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its VCDs.

214. Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

215. Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to make purchases of Defendant's VCDs.

216. As a direct and proximate result of Defendant's acts and omissions described herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

217. Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for VCDs.

218. Defendant intended its misrepresentations or omissions to induce Plaintiffs and Class members to make purchases or reimbursements of VCDs or had reckless disregard for same.

219. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have made purchases of Defendant's VCDS.

220. Plaintiffs and other Class Members were justified in relying on Defendant's misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, or the same or substantively identical omissions were not communicated, to each

Class Member.

221. Plaintiffs and other Class Members were damaged by reason of Defendant's misrepresentations or omissions alleged here.

**SIXTH COUNT**
**VIOLATION OF STATE CONSUMER PROTECTION LAWS**

222. Plaintiffs re-allege and incorporate paragraphs 1 to 157 as if fully set forth here.

223. Defendant has violated the consumer protection statutes as follows:

a. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendant has violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendant has violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendant has violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*

h. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

i. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

j. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

k. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

l. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

m. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

o. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

p. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

t. Defendant has engaged in unfair competition or unfair or deceptive acts or

practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

v. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*; Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

w. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

x. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

y. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

z. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

aa. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

bb. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

cc. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

dd. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

ee. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

ff. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

gg. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

hh. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

ii. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, et seq.;

jj. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

kk. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ll. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

mm. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

nn. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

oo. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

pp. Defendant has engaged in unfair competition or unfair or deceptive acts or

practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

qq. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

rr. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

ss. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

tt. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

uu. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

vv. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

ww. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

xx. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, et seq.;

Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.;*

yy. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

zz. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

aaa. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

224. Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

225. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendant's misconduct within the meaning of the above statutes.

226. To the extent applicable, Defendant knew, intended, or should have known that its fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages—an ascertainable loss—in an amount to be proved at trial.

## SEVENTH COUNT
## UNJUST ENRICHMENT

227. Plaintiffs re-allege and incorporate paragraphs 1 to 157 as if fully set forth here.

228. As alleged herein, Defendant was unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendant's VCDs.

229. Defendant profited immensely from introducing a carcinogen into the United States for human consumption. What's more, because Defendant's VCDs were adulterated and misbranded, their distribution and sale in the United States was illegal.

230. Plaintiffs and other Class Members were unjustly deprived of money obtained by Defendant as a result of the improper amounts paid for Defendant's VCDs. It would be inequitable and unconscionable for Defendant to retain the profit, benefit, and other compensation obtained from Plaintiffs and other Class Members as a result of its wrongful conduct alleged in this

Master Complaint. There is no adequate remedy at law for Plaintiffs and other Class members.

231. Plaintiffs and other Class Members are entitled to seek and do seek restitution from Defendant as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendant by virtue of its wrongful conduct.

**EIGHTH COUNT**
**NEGLIGENCE**

232. Plaintiffs re-allege and incorporate paragraphs 1 to 157 as if fully set forth here.

233. Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its VCDs.

234. Defendant owed a duty to Plaintiffs and the Class to ensure that the VCDs it sold in the United States were therapeutically equivalent to branded Chantix and complied with cGMPs and were not adulterated or misbranded.

235. Defendant owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of VCDs and victim of Defendant's fraudulent and deceptive activities. Defendant knew, or should have known, that its VCDs were not therapeutically equivalent to branded Chantix and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

236. Defendant failed to do this. Defendant inadequately oversaw the manufacture and sale of its own VCDs. Defendant knew that ignoring the manufacturing issues surrounding its VCDs would damage Plaintiffs and the Class and increase its own profits.

237. Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its VCDs complied with cGMPs

and was not adulterated or misbranded.

238. Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its VCDs.

239. Defendant breached duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

240. As a direct and proximate result of Defendant's negligent conduct, Plaintiffs and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

**NINTH COUNT**
**NEGLIGENCE PER SE**

241. Plaintiff re-allege and incorporate paragraphs 1 to 157 as if fully set forth here.

242. Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its VCDs.

243. Defendant owed a duty to Plaintiffs and the Class to ensure that the VCDs it sold in the United States were therapeutically equivalent to branded Chantix and complied with cGMPs and were not adulterated or misbranded.

244. Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted or adheres to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);

- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

245. Defendant failed to comply with federal cGMPs and federal adulteration

standards.

246. As a result of Defendant's failures to do so, Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

247. As a direct and proximate result of Defendant's negligent conduct, Plaintiffs and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

**PRAYER FOR RELIEF**

For these reasons, Plaintiffs pray for the following judgment:

A. An order certifying this action as a class action;

B. An order appointing Plaintiffs as Class Representatives, and appointing undersigned counsel as Class Counsel to represent the Class;

C. A declaration that Defendant is liable under each and every one of the above-enumerated causes of action;

D. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendant described above;

E. Payment to Plaintiffs and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action inan amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for the VCDs; the costs to replace or return VCDs because of recalls; and the increases in the amounts paid for non-adulterated, non-misbranded, VCDs in the wake of the recalls;

F. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

G. An award of statutory penalties to the extent available;

H. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

I. Such other and further relief as this Court may deem just, equitable, or proper.

**JURY DEMAND**

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

Dated: October 19, 2021.

**RIVERO MESTRE LLP**

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